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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,292	08/01/2001	Andrew P. McMahon	21508-022 Nat	5115

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EXAMINER	
NICHOLS, CHRISTOPHER J	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,292	MCMAHON ET AL.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 7-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 7-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2 and 7-9* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 30 December 2003 has been received and entered in full. Claims 1 and 2 have been amended and claims 3-6 and 10-20 have been cancelled. Claims 1, 2, and 7-9 are under examination.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

3. The Objection to the Specification as set forth at ¶4-8 pp. 2-3 of the previous Office Action (30 June 2003) is *withdrawn* in view of Applicant's submission of an Abstract (30 December 2003).

4. The Objection to claim 2 as set forth at ¶9 pp. 3 of the previous Office Action (30 June 2003) is *withdrawn* in view of Applicant's amendments (30 December 2003).

5. The Rejection of claim 3-6 and 21 under 35 U.S.C. §112 ¶1 as set forth at ¶10-22 pp. 3-9 of the previous Office Action (30 June 2003) is *moot* in view of Applicant's cancellation of said claims (30 December 2003).

Maintained Objections And/Or Rejections

Oath/Declaration

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Rejections - 35 USC § 112

7. Claims **1, 2, 7, 8,** and **9** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as set forth at ¶10-22 pp. 3-9 of the previous Office Action (30 June 2003).

8. Applicant traverses this rejection on the following grounds: **(a)** the overbreadth of the claims has been overcome by amending Wnt polypeptide to Wnt-1, more specifically SEQ ID NO: 1, **(b)** the claims only require an enriched population of cells which are responsive to SEQ ID NO: 1 to be isolated, **(c)** the significant contribution to the art provided by the present Inventors is which composition to use to achieve the desired effect of enriching for neuronal precursor cells, and **(d)** the Specification teaches how to achieve the claimed population of cells.

9. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

10. On "**(a)**", the overbreath of the claims (corresponding to "breadth of the claims" as a *Wands* factor), the claims are still broad in terms of "mammalian neural precursor cells". This limitation refers to a broad and diverse genus of cells which must be isolated, screened, and characterized as exhibiting a stem cell phenotype in the presence of SEQ ID NO: 1 (human Wnt-1). Therefore the claims as written still present a problem with the absolute breadth of the claims. The skilled artisan is not given any definite parameters to which to practice the invention. For instance, Kandel *et al.* Principles of Neural Science 4th Ed. "Chapter 53: The Generation and Survival of Nerve Cells" (1041-1062) teaches that mammalian neural precursor cells can pertain to multipotent, pluripotent, stem, precursor, and progenitor. Also such cells are found during embroygenesis, fetal development, as well as the juvenile and adult forms of mammals. Also the neural stem cell refers to any cells which have originated from the neural crest during development covering the entire range of the central and peripheral nervous system as well as the adrenal medulla, smooth muscle, melanocytes, and facial bones {see also Anderson (29 July 2000) "Genes, lineages and the neural crest: a speculative review." Phil. Trans. R. Soc. Lond. B **355**(1399): 953-964}.

11. On "**(b)**", the claims as written constitute an invitation to experiment. No mammalian neural precursor or mammalian dopaminergic neuron precursor cell population have been isolated. In fact, the Specification's guidance consists of a suggested protocol to screen, isolate, characterize, and then further purify/concentrate/enrich the desired mammalian neural precursor or mammalian dopaminergic neuron precursor cells once so identified. This presents an undue burden of experimentation on the skilled artisan. No anatomical structures are suggested, nor any specific developmental stage, or age (fetal, juvenile, adult) specified to guide the skilled artisan

in this unpredictable field of endeavor. Further US 6,040,180 (21 March 2000) Johe which reviews the difficulties and variance found in cell differentiation and states:

> "Results such as these illustrate that identifying CNS stem cells, defining conditions that stable maintain CNS stem cell properties for long-term, and controlling their differentiation into mature cell types are neither obvious nor predictable to those skilled in this art." (Col. 7 lines 54-60)

Thus the skilled artisan is given no sufficient guidance in an unpredictable filed of research to screen, isolate, characterize, and enrich a population of postulated mammalian neural precursor or mammalian dopaminergic neuron precursor cells.

12. On "**(c)**" and "**(d)**", as noted above, no population with the desired properties has been presented. The Specification's guidance consists of a prophetic suggestion to screen, isolate, characterize, and then further purify/concentrate/enrich the desired mammalian neural precursor or mammalian dopaminergic neuron precursor cells. Further Ikeya *et al.* (30 October 1997) "Wnt signaling required for expansion of neural crest and CNS progenitors." Nature **389**(6654): 968-970 teaches that it is unlikely that Wnt-1 is involved in differentiation. Ikeya *et al.* teach that Wnt-1 is a well-characterized mitogen but does not appear to have any effects on differentiation *per se* and is held to be a proliferative factor (pp. 970). In addition, Vescovi *et al.* (May 2001) "The neural stem cells and their transdifferentiation capacity." Biomed Pharmacother **55**(4): 201-205 teach that neural stem cells can form non-CNS tissues such as blood and skeletal muscle (Table I). Therefore the claims as currently constitutes an invitation to experiment as the art does not teach Wnt-1 as a differentiation factor and the outcome of neural stem cell differentiation can vary widely.

13. Claims **1, 2, 7, 8,** and **9** are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

14. The independent claims require enriched populations of mammalian precursor cells which respond to Wnt-1 (SEQ ID NO: 1) but the Specification does not demonstrate that said cells were actually identified, isolated, or characterized.

15. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in the claim that is sufficiently disclosed is a partial structure in the form of a recitation of *a desired product*. The specification does not identify any particular portion of the structure that must be conserved, nor does it provide a disclosure of structure/function correlation. The distinguishing characteristics of the claimed genus are not described. Accordingly, the specification does not provide adequate written description of the claimed genus.

16. To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient

detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572.

17. See *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003). In *University of Rochester v. G.D. Searle & Co.* a patent directed to method for inhibiting prostaglandin synthesis in human host using unspecified compound, in order to relieve pain without side effect of stomach irritation, did not satisfy written description requirement of 35 U.S.C. §112, since patent described the compound's desired function of reducing activity of enzyme PGHS-2 without adversely affecting PGHS-1 enzyme activity, but did not identify said compound, since invention consists of performing "assays" to screen compounds in order to discover those with desired effect. The patent did not name even one compound that assays would identify as suitable for practice of invention, or provide information such that one skilled in art could identify suitable compound. And since specification did not indicate that compounds are available in public depository, the claimed treatment method cannot be practiced without compound. Thus the inventors cannot be said to have "possessed" claimed invention without knowing of a compound or method certain to produce compound. Thus said patent constituted an invitation to experiment to first identify, then characterize, and then use a therapeutic a class of compound defined only by their desired properties.

18. Therefore the claims fail to meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision.

Summary

19. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Elyaben C. Kemmerer

CJN
February 19, 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER